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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,765	09/15/2003	David H. Kil	14255-035001 / ARC01-201	1510
26161 7590 03/30/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER SIMS, JASON M	
			ART UNIT	PAPER NUMBER
			1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,765	KIL, DAVID H.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 19-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 30-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 1/3/2007, have been fully considered but they are not deemed to be persuasive.

Applicants have amended their claims, filed 1/3/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Applicant has newly added claims 30-35 in the reply filed 1/3/2007, which is acknowledged and has been entered.

Claims 1-18 and 30-35 are the current claims hereby under examination.

Specification

Applicant has amended the specification to no longer contain browser executable code and therefore the objection to the specification has been withdrawn.

Claim Objections

The applicant has amended their claims to properly define the acronym ROI and therefore the objection to claims 1-3, 6, 9-11, and 15-17 has been withdrawn.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-6, 8-9, 11, 13-15, 17, and 30-35 are drawn to a process. A statutory process must include a final resulting step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v.

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Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to 9-- process, machine, manufacture, or composition of matter--but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-2, 4-6, 8-9, 11, 13-15, 17, and 30-35 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a final resulting step of a physical transformation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4-6, 8-9, 11, 13-15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Akselrod et al. (US P/N 6, 858, 007).

The claims are directed to a method of image analysis comprising transforming an image into a feature space, extracting features, ranking the extracted features,

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classifying the image into regions of interest, and transmitting the regions of interest for laser capture microdissection.

Akselrod et al. teaches claims 1, 11, and 17 at col. 3, lines 5-10, col. 5, lines 29-50, col. 6, lines 25-45, col. 7, lines 2-20 and lines 25-54, col. 9, lines 39-67, col. 10, lines 10-18 and lines 39-51, col. 11, lines 50-61, and col. 15, lines 19-25. Akselrod et al. discusses at col. 3, obtaining an cross-sectional image of an adnexal mass, which represents receiving an image. Akselrod et al. discusses at col. 6, defining a set of parameters of the obtained image and presenting them in a feature space, which represents transforming the image into a feature space. Akselrod et al. discusses at col. 15, selecting a ROI at a pixel level of processing. Akselrod et al. discusses at col. 9, a process of segmentation in image analysis, which represents selecting an ROI and non-ROI and extracting features from the ROI. Akselrod et al. discusses at col. 5, classifying a mass, which requires extracting information from the obtained image, which represents extracting features from the ROI. Akselrod et al. discusses at col. 7, extracting boundaries using a edge detection algorithm, which represents extracting features of the ROI at a pixel level. Additionally, Akselrod et al. discusses at col. 7, extracting boundaries of an entire object and applying thresholds to sub-ranges of the object, which has been converted into a histogram, and includes a comparison between objects and background information about the image which represents selecting at least one non-ROI at a pixel level of processing and extracting features from the non-ROI at a pixel level of processing where the background regions are really non-ROI regions. Akselrod et al. discusses at col. 10 and col. 14, using a minimum cross entropy

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thresholding, MCE, to rank gray scale values of pixels, which represent extracted features and making a histogram of the object image, which represents ranking the extracted features based on feature performance and recording the ranked extracted features. In addition, this algorithm is used to distinguish between tissue and fluid, a segmentation process which represents choosing a classification algorithm and classifying the image into regions of interest and recording the ROIs based on pixel processing.

Claim 2 is taught by Akselrod et al. at col. 10, lines 10-18 and lines 39-51 and col. 14. Akselrod et al. discusses using a classifying algorithm, MCE, in a segmentation process, which segments an obtained image into regions of tissue and fluid, which represents segmenting an image into ROIs and non-ROIs and making a histogram and applying a thresholding program for classifying, which represents selecting one or more pixels from the image.

Claims 4-5, 8,13, and 14 are taught by Akselrod et al. at col. 15, lines 19-25 and col. 7. Akselrod et al. discusses various sizes of windows being tested and computed and analyzing an obtained image by using edge and region detection algorithms to detect a region of an image and then doing further analysis by analyzing sub-regions of the region of the image, both of which represent a second and third level of processing comprising sub-image processing and object processing.

Claim 6 is taught by Akselrod et al. as applied to combination of claims 1, 4, and 5 discussed above.

Claims 9 and 15 are taught by Akselrod et al. at col. 7, lines 35-54. Akselrod et al. discusses using a edge detection algorithm to detect an object, which represents object processing where at least one polygonal ROI is processed.

Claim 11 is taught by Akselrod et al. as applied to the combination of claims 1 and 8-9 discussed above.

Claim 17 is taught by Akselrod et al. as applied to the combination of claims 1 and 14-15 discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3, 7, 10, 12, 16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akselrod et al. (US P/N 6, 858, 007) as applied to claims 1, 6, 11, and 17 above, and further in view of Levenson et al. (US P/N 6, 750, 964).

Akselrod et al discusses at col. 6, lines 55-64 analyzing a 3-D image. This invention relates to diagnosing lumps in the breast, which are cancerous and would need to be removed. Akselrod et al. does not teach a method of utilizing image analysis and the edge and region detection algorithms for use in a laser capture microdissection.

Levenson et al. at col. 2, lines 45-61 teaches a method of laser capture microdissection after target image analysis.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the analysis and diagnosing methods taught by Akselrod et al. with the method of laser capture microdissection taught by Levenson et al. because after diagnosing an individual with cancer it is a necessary step to remove the benign or potentially malignant tumor from the patient. In addition, it would be an inherent step in the process where the information obtained by performing the image analysis steps of Akselrod et al. would be transmitted and communicated to the station used to perform the laser capture microdissection.

Response to Arguments

Applicant's arguments with respect to the rejection of claims 1-2, 4-6, 8-9, 11, 13-15, and 17 under 35 USC 101 have been fully considered but they are not persuasive. Applicant argues that a prima facie case has not been established showing that the rejected claims are found to be non-statutory. Additionally, applicant has amended claim 1 to output an analysis result.

Applicant's amendment and arguments are not found persuasive and have been addressed in the above rejection of claims 1-2, 4-6, 8-9, 11, 13-15, 17 and 30-35 under 35 USC 101. Although applicant has amended claim 1 to output a result, it is still considered non-statutory because the result has not been outputted specifically to read on statutory subject matter, such as a display, an end user, another networked computer, or a computer memory as stated above in the rejection under 35 USC 101.

Applicant's arguments with respect to the rejection of claims 1-2, 4-6, 8-9, 11, 13-15, and 17 under 35 USC 102 (e) have been fully considered but they are not persuasive. Applicant argues that Akselrod does not perform a step of "ranking the extracted features based on feature performance for successful detection of a selected ROI at a pixel level of processing" according to the method recited in the specification.

Applicant's arguments are not found persuasive. Although the specification describes a preferred method of performing the recited step of ranking the extracted features, the claims are not limited to the method described in the specification.

Akselrod at col. 13, lines 50-67 and col. 14-16 describes a method of ranking pixel values where the pixels are ranked to form a decision curve, which is ranking the clusters of pixels where a cluster below a certain threshold would indicate a particular region of interest, such as a filled region, where a cluster above the threshold would indicate something else. Any extracted data about the clusters can be used to optimize the weights in order to obtain a better decision curve, which is a method of ranking the extracted features based on feature performance for successful detection of a selected ROI at a pixel level of processing.

Applicant's arguments with respect to the rejection of claims 3,7,10,12,16, and 18 under 35 USC 103 have been fully considered but they are not persuasive.

Applicant argues that Akselrod does not perform a step of "ranking the extracted features based on feature performance for successful detection of a selected ROI at a pixel level of processing" according to the method recited in the specification.

Applicant's arguments are not found persuasive for the reasons discussed above. Therefore the rejections of claims under 35 USC 102 (e) and 35 USC 103 have been maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ram Shukla can be reached via telephone (571)-272-0735.

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Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

John S. Brusca 27 March 2004
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER